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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

RHIANN LINDBERG INDIVIDUALLY)	Case No.:
AND AS MOTHER, GENERAL GUARDIAN)	
OF R.L., A MINOR,)	COMPLAINT
)	(Jury Trial Demanded)
<i>Plaintiffs,</i>)	
)	
v.)	
)	
CVS PHARMACY, INC.)	
)	
<i>Defendant.</i>)	

COMPLAINT

Plaintiff Rhiann Lindberg and Plaintiff R.L., pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendant CVS Pharmacy, Inc., (hereinafter, “CVS” or “Defendant”) and in support state the following:

1. This is an action brought on behalf of Plaintiffs, Rhiann Lindberg (hereinafter, “Plaintiff Mother”), the mother and guardian of R.L. (hereinafter, “Plaintiff Child”), a minor, arising out of the failure of Defendant to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter “APAP”) and its propensity to cause autism spectrum disorder (hereinafter, “ASD”) and attention-deficit/hyperactivity disorder (hereinafter, “ADHD”) in children. As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendant entirely failed its duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs’ injuries and associated damages.

STATEMENT OF PARTIES

3. At all material times, Plaintiffs have been citizens and residents of Novato, California, and the United States.

4. CVS is incorporated in Woonsocket, Rhode Island with its principal place of business in Woonsocket, Rhode Island.

5. CVS is a multinational company involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter store brand, “CVS Health” (hereinafter, the “CVS Health APAP”).

6. CVS is individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from Defendant’s design, manufacture, marketing, labeling, distribution, sale, and placement of the defective CVS Health APAP into the market, effectuated directly and indirectly

1 through its agents, servants, employees, and/or owners, all acting within the course and scope of
 2 its agencies, services, employments, and/or ownership.

3 7. CVS is vicariously liable for the acts and/or omissions of its employees and/or
 4 agents, who were at all material times acting on behalf of CVS and within the scope of its
 5 employment or agency.

6 **VENUE AND JURISDICTION**

7 8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on
 8 complete diversity of citizenship between Plaintiffs and Defendant. *See supra* ¶¶ 3–4.

9 9. The amount in controversy exceeds \$75,000.

10 10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or
 11 omissions giving rise to Plaintiffs' claims occurred in this judicial district.

12 11. Defendant has and continues to conduct substantial business in the State of
 13 California and in this District, distributes the CVS Health APAP in this District, receives
 14 substantial compensation and profits from sales of the CVS Health APAP in this District, and has
 15 made material omissions and misrepresentations and breaches of warranties in this District, so as
 16 to subject Defendant to in personam jurisdiction in this District.

17 12. Defendant is registered to transact business in California.

18 **FACTS COMMON TO ALL COUNTS**

19 **APAP Is Marketed as the Safe Pain Reliever for Pregnant Women, 20 but APAP Can Cause Neurodevelopment Disorders in Children, such as ASD and ADHD**

21 13. APAP was initially discovered in the late 1800's.

22 14. APAP is sold in billions of units annually in North America alone.

23 15. APAP is widely used by pregnant women to relieve pain during the term of their
 24 pregnancy.

25 16. APAP was introduced to the US market in 1955 as the first aspirin-free pain
 26 reliever.

27 17. APAP has long been marketed as the safest, and the *only* appropriate, over-the-
 28 counter pain relief drug on the market for pregnant women.

1 18. More than 65% of women in the United States use APAP during pregnancy.

2 19. Based upon information and belief, a majority of women who use APAP during
3 pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and infection.

4 20. These pregnant women electively choose to take APAP because Defendant has
5 marketed APAP as a safe pain reliever for pregnant women.

6 21. However, increasing experimental and epidemiological research shows that
7 prenatal exposure to APAP alters fetal development, which significantly increases the risks of
8 neurodevelopmental disorders, including but not limited to, ASD and ADHD.

9 22. Undisturbed development of the human brain in utero is vital to the health and
10 wellness of a child's development. The human brain is vulnerable and extremely sensitive in utero.

11 23. During this sensitive time-period in utero, certain chemicals have been found to
12 cause permanent brain injury at low exposure levels.

13 24. Once ingested by the mother, APAP is known to readily cross the placenta and
14 blood-brain barrier.

15 25. ASD is a serious neurological and developmental disorder that affects how people
16 interact with others, communicate, learn, and behave.

17 26. There are three functional levels of ASD, with Level 1 requiring support with
18 activities of daily living, Level 2 requiring substantial support with activities of daily living, and
19 Level 3 requiring very substantial support with activities of daily living.

20 27. Treatments for ASD include behavioral management therapy, cognitive behavior
21 therapy, joint attention therapies, medications, occupational therapy, physical therapy, social skill
22 training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no cure.

23 28. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
24 hyperactivity, and impulsiveness.

25 29. ADHD begins in childhood and persists through adulthood. ADHD contributes to
26 low self-esteem, troubled relationships, and difficulty with school, work, and familial
27 relationships.

1 30. Treatments for ADHD, include, but are not limited to, chronic medication usage
2 and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

3 31. Adults with childhood ADHD are expected to earn \$1.25 million less than adults
4 without ADHD over their lifetime, potentially reaching retirement with up to a 75 percent lower
5 net worth.

6 32. In or around 2018, the Center for Disease Control and Prevention (“CDC”) found
7 that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

8 33. This represents an increase from a prior CDC finding that 1 in 68 U.S. children
9 born in 2002 have ASD, which already represented a more than a 100% increase compared with
10 children born a decade prior.

11 34. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly
12 325,000 children per year.

13 35. Parental awareness and changes in diagnoses do not account for the rapid rise in
14 these diagnoses of neurodevelopmental disorders.

15 36. Rather, neurotic exposures, such as prenatal APAP exposure, explain a trending
16 increase in diagnosis.

17 37. For years, the scientific community has published studies showing that prenatal
18 ingestion of APAP can cause ASD and ADHD.

19 38. For instance, since 2013, there have been six European birth cohort studies,
20 examining over 70,000 mother-child pairs, showing the association between prenatal use of APAP
21 and ASD and ADHD.

22 39. At this time, the overall body of scientific evidence shows that prenatal use of
23 APAP can cause ASD and ADHD in the child.

24 40. During all relevant times herein, Defendant was engaged in the business of
25 manufacturing and selling the CVS Health APAP in the United States, and the weight of the
26 scientific evidence available showed prenatal exposure to APAP significantly increases the risk of
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1 neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited
2 to ASD and ADHD.

3 41. The scientific evidence regarding the risks of in utero exposure of APAP was
4 available to Defendant, and Defendant knew or should have known that prenatal use of APAP can
5 cause ASD and ADHD.

6 42. Based on information and belief, Defendant has concealed the prenatal APAP
7 exposure-neurodevelopmental link from consumers, like Plaintiff Mother, in part by not reporting
8 the link to the FDA, which relies on drug manufacturers to bring new information about a drug to
9 the agency's attention.

10 43. Moreover, despite knowing that prenatal use of APAP can cause ASD and ADHD,
11 Defendant continues to market the CVS Health APAP as the safe pain reliever for pregnant
12 women, making mothers believe they are choosing a safe drug for even minor aches, pains, and
13 headaches.

14 **Plaintiff Mother Took CVS Health APAP while Pregnant,**
15 **and It Caused ASD and ADHD in Plaintiff Child**

16 44. Plaintiff Mother began using the CVS Health APAP in or around March 2006,
17 when she was pregnant with Plaintiff Child, through November 2006, when Plaintiff Child was
18 born.

19 45. Throughout Plaintiff Mother's pregnancy, she took the CVS Health APAP about
20 once a week to treat general aches and pains.

21 46. Plaintiff Mother associated these aches and pains with her pregnancy.

22 47. Plaintiff Mother purchased and took the CVS Health APAP in Marin County,
23 California.

24 48. Plaintiff Mother electively took the CVS Health APAP while pregnant.

25 49. Plaintiff Mother believed it was safe for her to take the CVS Health APAP during
26 her pregnancy.

27 50. There is no warning on the CVS Health APAP labels specifically addressing the
28 risks of a child developing ADHD if a mother ingests APAP while pregnant.

51. Had Plaintiff Mother known of the risk of taking APAP while pregnant, specifically that it could cause ADHD in her child, she would not have taken the CVS Health APAP.

52. Plaintiff Child was born on November 12, 2006.

53. Plaintiff Mother started to have concerns about Plaintiff Child's development when he was around five years old.

54. Plaintiff Child was diagnosed with ASD when he was around eight years old.

55. Plaintiff Child was also diagnosed with ADHD.

56. Plaintiff Child has behavioral issues because of his ASD and ADHD.

57. Plaintiff Child also has difficulty in school because of his ASD and ADHD.

58. These issues have a huge impact on Plaintiff Mother and Plaintiff Child.

59. Plaintiff Child's ASD and ADHD has placed an incredible mental, physical, emotional, and financial strain on Plaintiff Mother.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

60. Due to Defendant's acts of fraudulent concealment, Defendant is estopped from relying on any statutes of limitations or repose. Such acts include Defendant's intentional concealment from Plaintiff Mother and the general public that APAP is defective when there is prenatal exposure, while continuing to market the CVS Health APAP with the adverse effects described in this Complaint.

61. Given Defendant's affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which Defendant had exclusive control—and because Plaintiff Mother could not reasonably have known that the CVS Health APAP was defective, Defendant is estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

COUNT I: STRICT LIABILITY – FAILURE TO WARN

62. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

63. At the time of Plaintiffs' injuries, the CVS Health APAP was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff Mother, because they lacked an adequate warning.

64. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and promoting the CVS Health APAP, which was defective and unreasonably dangerous to consumers, including Plaintiff Mother, because they did not contain adequate warnings or instructions concerning the dangerous characteristics of ingesting APAP during pregnancy. These actions were under the ultimate control and supervision of Defendant. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, labeled, promoted, and sold the CVS Health APAP within this District and aimed the marketing at the ultimate consumer. Defendant was at all relevant times involved in the retail and promotion of the CVS Health APAP marketed and sold in this District.

65. Defendant had a duty to warn of the risks associated with the use of the CVS Health APAP.

66. The CVS Health APAP ingested by Plaintiff Mother during pregnancy was in the same or substantially similar condition as it was when it left possession of the Defendant.

67. Defendant expected and intended the CVS Health APAP to reach users such as Plaintiff Mother in the condition in which the CVS Health APAP was sold.

68. Plaintiff Mother did not materially alter the CVS Health APAP prior to ingestion.

69. Plaintiff Mother ingested the CVS Health APAP as indicated on the CVS Health APAP labels.

70. Plaintiff Mother was unaware of the defects and dangers of the CVS Health APAP and was unaware that prenatal exposure increases the risk of brain and behavioral development of children in utero.

71. The labels on the CVS Health APAP to consumers lack any warning specific to pregnant women. The information that Defendant did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff

1 Mother to utilize the products safely and with adequate protection, or decide to not ingest the CVS
2 Health APAP at all.

3 72. This alleged failure to warn is not limited to the information contained on the CVS
4 Health APAP's labeling. Defendant was able, in accord with federal law, to comply with relevant
5 state law by disclosing the known risks associated with APAP through other non-labeling
6 mediums, i.e., promotion, advertisements, public service announcements, and/or public
7 information sources. But Defendant did not disclose these known risks through any medium.

8 73. At all relevant times, Defendant had a duty to properly test, develop, design,
9 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the
10 CVS Health APAP; provide proper warnings for the CVS Health APAP; and take such steps as
11 necessary to ensure the CVS Health APAP did not cause users and consumers, and their children,
12 to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn Plaintiff
13 Mother of dangers associated with APAP. Defendant, as a manufacturer, seller, and/or distributor
14 of pharmaceutical medication, is held to the knowledge of an expert in the field.

15 74. At the time of manufacture, Defendant could have provided the warnings or
16 instructions regarding the full and complete risks of the CVS Health APAP because Defendant
17 knew or should have known of the unreasonable risks of ASD and ADHD associated with prenatal
18 exposure to and/or the use of such products.

19 75. At all relevant times, Defendant failed and deliberately refused to investigate,
20 study, test, or minimize the dangers to consumers of the CVS Health APAP and to those who
21 would foreseeably use or be harmed by the CVS Health APAP, including Plaintiffs.

22 76. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the
23 significant increased risk of neurodevelopmental disorders in children exposed to APAP
24 prenatally, including but not limited to ASD and ADHD.

25 77. Defendant failed to adequately inform reasonably foreseeable consumers, like
26 Plaintiff Mother, of the proper usage of the CVS Health APAP.

1 78. Even though Defendant knew or should have known that APAP posed a grave risk
2 of harm to Plaintiff Child, Defendant failed to exercise reasonable care to warn of the dangerous
3 risks associated with use and prenatal exposure.

4 79. Plaintiff Mother was exposed to the CVS Health APAP without knowledge of their
5 dangerous characteristics.

6 80. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the
7 CVS Health APAP while using them for their intended or reasonably foreseeable purposes,
8 without knowledge of their dangerous characteristics.

9 81. Plaintiff Mother could not have reasonably discovered the defects and risks
10 associated with the CVS Health APAP prior to or at the time of Plaintiff consuming APAP.
11 Plaintiff Mother relied upon the skill, superior knowledge, and judgment of Defendant to know
12 about and disclose serious health risks associated with using the CVS Health APAP.

13 82. If Plaintiff Mother had been properly warned of the defects, dangers, and risks
14 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest the
15 CVS Health APAP while pregnant.

16 83. Defendant is liable to Plaintiffs for injuries caused by Defendant's negligent or
17 willful failure, as described above, to provide adequate warnings or other relevant information and
18 data regarding the appropriate use of the CVS Health APAP and the risks associated with the use
19 of APAP.

20 84. As a direct and proximate result of Defendant placing defective CVS Health APAP
21 into the stream of commerce, and Plaintiff Mother's ingestion of the CVS Health APAP during
22 pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to develop ASD and
23 ADHD.

24 85. As a direct and proximate result of Defendant placing defective CVS Health APAP
25 into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and
26 suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.
27 Plaintiffs respectfully seek all damages to which they may be legally entitled.
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COUNT II: NEGLIGENCE

86. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

87. Although Defendant had a duty to use reasonable care in testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing written instructions and warnings for the CVS Health APAP, Defendant failed to do so.

88. Defendant, directly or indirectly, caused the CVS Health APAP to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, promoted, and sold the CVS Health APAP within this district and aimed at a consumer market within this district.

89. Defendant knew, or in the exercise of reasonable care should have known, that the CVS Health APAP was defectively and unreasonably designed and/or manufactured, and/or marketed, and was unreasonably dangerous and likely to injure persons that were prenatally exposed to them. Defendant knew or should have known that Plaintiff Mother was unaware of the dangers and defects inherent in the CVS Health APAP when she was ingesting them during her pregnancy with Plaintiff Child.

90. At all relevant times, Defendant had a duty to exercise reasonable care in the marketing, advertisement, promotion, and sale of the CVS Health APAP. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using APAP during pregnancy and appropriate, complete, and accurate warnings concerning the potential adverse effects of APAP and, in particular, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

91. At all relevant times, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of APAP ingestion while pregnant and, specifically, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

1 92. Defendant failed to provide any kind of warning to pregnant consumers, like
2 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders
3 in children through prenatal exposure to APAP.

4 93. Accordingly, at all relevant times, Defendant knew or, in the exercise of reasonable
5 care, should have known that use of the CVS Health APAP could cause Plaintiffs' injuries, and
6 thus, create a dangerous and unreasonable risk of injury to the users of these products, including
7 Plaintiffs.

8 94. As such, Defendant breached its duty of reasonable care and failed to exercise
9 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
10 supply, promotion, advertisement, packaging, sale, and distribution of the CVS Health APAP, in
11 that Defendant manufactured and produced defective CVS Health APAP, which carry the
12 significantly increased risk of causing neurodevelopmental disorders in children through prenatal
13 exposure to APAP; knew or had reason to know of the defects inherent in the CVS Health APAP;
14 knew or had reason to know that a user's or consumer's use of the CVS Health APAP created a
15 significant risk of harm and unreasonably dangerous side effects; and failed to prevent or
16 adequately warn of these risks and injuries.

17 95. Defendant had a duty to disclose the truth about the risks associated with APAP in
18 its promotional efforts outside of the context of labeling. Defendant was negligent in its promotion
19 of APAP outside of the labeling context by failing to disclose material risk information as part of
20 its promotion and marketing of the CVS Health APAP, including through the internet, television,
21 and print advertisements.

22 96. Despite Defendant's ability and means to investigate, study, and test the CVS
23 Health APAP and to provide adequate warnings, Defendant failed to do so. Indeed, Defendant
24 wrongfully concealed information and further made false and/or misleading statements concerning
25 the safety and use of APAP.

26 97. Defendant's negligence included:
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- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the CVS Health APAP while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of APAP and the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and, consequently, the risk of serious harm associated with human use of APAP during pregnancy;
- b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the CVS Health APAP was safe for its intended consumer use and unborn children;
- c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendant could reasonably foresee would use the CVS Health APAP;
- d. Failing to disclose to Plaintiff Mother, users, consumers, and the general public that use of APAP during pregnancy presents severe risks of neurodevelopmental disorders in children exposed to APAP prenatally;
- e. Failing to warn Plaintiff Mother, users, consumers, and the general public that the CVS Health APAP's risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff Mother and other users and/or consumers;
- f. Representing that the CVS Health APAP was safe for their intended purposes for pregnant women when, in fact, Defendant knew or should have known the CVS Health APAP was not safe for their intended purposes;
- g. Declining to make or propose any changes to the CVS Health APAP's labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women;

- h. Advertising, marketing, and recommending the use of the CVS Health APAP, while concealing and failing to disclose or warn of the dangers known by Defendant to be caused by the use of or exposure to APAP;
- i. Continuing to disseminate information to its consumers and the general public, which indicates or implies that the CVS Health APAP are not unsafe for pregnant consumer use; and
- j. Continuing the manufacture and sale of the CVS Health APAP with the knowledge that the CVS Health APAP was unreasonably unsafe and dangerous.

98. Defendant knew and/or should have known that it was foreseeable that children such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the CVS Health APAP to consumers, like Plaintiff Mother.

99. Plaintiff Mother did not know the nature and extent of the injuries that could result in her child from the intended use of and/or exposure to APAP prenatally.

100. Defendant's negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendant's negligence, Plaintiff Child would not have developed ASD and ADHD.

101. Defendant's conduct, as described above, was reckless. Defendant regularly risked exposing Plaintiff Mother to the CVS Health APAP while pregnant with Plaintiff Child, with full knowledge of the dangers of the CVS Health APAP and that it could cause ASD and/or ADHD in Plaintiff Child. Defendant made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff Mother. Defendant's reckless conduct therefore warrants an award of punitive damages.

102. As a direct and proximate result of Defendant placing the defective CVS Health APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT III: BREACH OF EXPRESS WARRANTY

103. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

104. At all material times, Defendant manufactured, marketed, sold, distributed, and otherwise placed into the stream of commerce the CVS Health APAP. These actions were under the ultimate control and supervision of Defendant.

105. In advertising, marketing, and promoting the CVS Health APAP to consumers, like Plaintiff Mother, Defendant expressly warranted that the CVS Health APAP was safe for use and reasonably fit for their intended purposes. In advertising, marketing, and otherwise promoting the CVS Health APAP, Defendant intended for pregnant consumers to rely upon its representations regarding safety and fitness, in an effort to induce them to purchase and consume the CVS Health APAP during pregnancy to relieve pain.

106. Defendant expressly warranted to Plaintiff Mother and pregnant consumers that the CVS Health APAP was safe for ingestion during pregnancy.

107. Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of the CVS Health APAP, including a duty to:

- a. ensure that the CVS Health APAP did not cause users and their unborn children unreasonably dangerous side effects;
- b. warn of dangerous and potentially incurable side effects; and
- c. disclose adverse material facts, such as the true risks associated with the use of and exposure to APAP during pregnancy, when making representations to users, consumers, and the general public, including Plaintiff Mother.

108. Defendant had the ability to properly disclose the risks associated with APAP usage during pregnancy through multiple channels, not just labeling.

109. At all relevant times, Defendant expressly represented and warranted to the purchasers of the CVS Health APAP, by and through statements made by Defendant in labels, publications, brochures, and other written materials intended for consumers and the general public,

1 that the CVS Health APAP was safe to human health and the environment, effective, fit, and proper
2 for their intended use. Defendant advertised, labeled, marketed, and promoted the CVS Health
3 APAP, representing the quality to consumers and the public in such a way as to induce their
4 purchases or use, thereby making an express warranty that the CVS Health APAP would conform
5 to the representations.

6 110. The representations about the CVS Health APAP, as set forth herein, contained or
7 constituted affirmations of fact or promises made by the seller to the buyer, which related to the
8 goods and became part of the basis of the bargain, creating an express warranty that the goods
9 would conform to the representations.

10 111. Defendant breached express representations and warranties made to Plaintiff
11 Mother, with respect to the CVS Health APAP, including the following:

- 12 a. Defendant represented through its labeling, advertising, and marketing materials
13 that the CVS Health APAP was safe, and intentionally withheld and concealed
14 information about the risks of serious injury associated with use of APAP and by
15 expressly limiting the risks associated with use within its warnings and labels; and
16 b. Defendant represented that the CVS Health APAP was safe for use and
17 intentionally concealed information that demonstrated that APAP carries the
18 significantly increased risk of causing neurodevelopmental disorders in children
19 through prenatal exposure to APAP, and that the CVS Health APAP, therefore, was
20 not safer than alternatives available on the market.

21 112. Plaintiff Mother detrimentally relied on the express warranties and representations
22 of Defendant concerning the safety and/or risk profile of APAP in deciding to purchase the CVS
23 Health APAP. Plaintiff Mother reasonably relied upon Defendant to disclose known defects, risks,
24 dangers, and side effects of APAP. Plaintiff Mother would not have purchased or used the CVS
25 Health APAP had Defendant properly disclosed the risks associated with the CVS Health APAP,
26 either through advertising, labeling, or any other form of disclosure.
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1 113. Plaintiff Mother had no knowledge of the falsity or incompleteness of Defendant's
2 statements and representations concerning the CVS Health APAP.

3 114. Plaintiff Mother used and/or was exposed to APAP as researched, developed,
4 designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted,
5 sold, or otherwise released into the stream of commerce by Defendant.

6 115. Had the warnings, labels, advertisements, or promotional material for the CVS
7 Health APAP accurately and adequately set forth the true risks associated with the use of such
8 products, including Plaintiffs' injuries, rather than expressly excluding such information and
9 warranting that the CVS Health APAP was safe for their intended use, Plaintiffs could have
10 avoided the injuries complained of herein.

11 116. As a direct and proximate result of Defendant's breach of express warranty,
12 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
13 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages
14 to which they may be legally entitled.

15 **COUNT IV: BREACH OF IMPLIED WARRANTY**

16 117. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

17 118. At all material times, Defendant manufactured, marketed, sold, distributed, and
18 otherwise placed the CVS Health APAP into the stream of commerce.

19 119. At all material times, Defendant intended for the CVS Health APAP to be
20 consumed and ingested by pregnant women, like Plaintiff Mother; and Defendant impliedly
21 warranted that the CVS Health APAP and its component parts were of merchantable quality, safe,
22 fit for such use, and adequately tested.

23 120. Defendant was aware that consumers, including Plaintiff Mother, would consume
24 and ingest the CVS Health APAP as directed by the products' labels and promotional materials.
25 Therefore, Plaintiff Mother was a foreseeable user of the CVS Health APAP.
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1 121. But Defendant failed to disclose that APAP has dangerous propensities when used
2 as intended and that use of the CVS Health APAP carries an increased risk of developing severe
3 injuries, including Plaintiff Child's injuries.

4 122. The CVS Health APAP was expected to reach, and did in fact reach consumers,
5 including Plaintiff Mother, without substantial change in the condition in which they were
6 manufactured and sold by Defendant.

7 123. Plaintiff Mother was an intended beneficiary of the implied warranties made by
8 Defendant to purchasers of the CVS Health APAP.

9 124. In reliance upon Defendant's implied warranties, Plaintiff Mother used the CVS
10 Health APAP as indicated, and in the foreseeable manner normally intended, recommended,
11 promoted, and marketed by Defendant.

12 125. Defendant breached its implied warranties to Plaintiffs in that the CVS Health
13 APAP was not of merchantable quality, nor were they safe or fit for their intended use or
14 adequately tested.

15 126. The harm caused by the CVS Health APAP far outweighed their benefit, rendering
16 the CVS Health APAP more dangerous than an ordinary consumer or user would expect and more
17 dangerous than alternative products.

18 127. As a direct and proximate result of Defendant's breach of express warranty,
19 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
20 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages
21 to which they may be legally entitled.

22 **COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

23 128. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

24 129. Plaintiff Mother purchased and used the CVS Health APAP for primarily personal
25 use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of
26 Defendant's actions in violation of the consumer protection laws.

1 130. Had Defendant not engaged in the deceptive conduct described in this Complaint,
2 Plaintiff would not have purchased and/or paid for the CVS Health APAP, and Plaintiffs would
3 not have incurred related injury medical costs.

4 131. Defendant engaged in wrongful conduct while at the same time obtaining under
5 false pretenses moneys from Plaintiff for the CVS Health APAP. Those moneys would not have
6 been paid had Defendant not engaged in unfair and deceptive conduct.

7 132. Defendant engaged in the following unfair methods of competition or deceptive
8 acts or practices, which are proscribed by law:

9 A. representing that goods or services have characteristics, ingredients, uses,
10 benefits, or qualities they do not have;

11 B. advertising goods or services with the intent not to sell them as advertised;
12 and

13 C. engaging in fraudulent or deceptive conduct creating a likelihood of
14 confusion or misunderstanding.

15 133. Plaintiffs were injured by the cumulative nature of Defendant's conduct. The
16 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and
17 sell the CVS Health APAP. Each aspect of Defendant's conduct combined to artificially create
18 sales of the CVS Health APAP.

19 134. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade
20 practices in the design, labeling, development, manufacture, promotion, and sale of the CVS
21 Health APAP.

22 135. Defendant's deceptive, unconscionable, or fraudulent representations and material
23 omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive acts and trade
24 practices in violation of the federal and state consumer protection statutes listed below.

25 136. Defendant's actions, as complained of in this Complaint, constitute unfair
26 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation
27 of the federal and state consumer protection statutes listed below.

1 137. Defendant has engaged in unfair competition, or unfair or deceptive acts or trade
2 practices, or has made false representations under the following statutes:

- 3 • 15 U.S.C. §§ 2301–12 (1982);
- 4 • Cal. Bus & Prof. Code § 17200, *et seq.* (Unfair Competition Law (“UCL”));
- 5 • Cal. Civ. Code § 17500 (False Advertising Law (“FAL”));
- 6 • Cal. Civ. Code § 1750 *et seq.* (Consumer Legal Remedies Act (“CLRA”)).

7 138. To protect consumers against unfair, deceptive, fraudulent, and unconscionable
8 trade and business practices, and false advertising, Defendant, as the supplier, manufacturer,
9 advertiser, and seller, is subject to liability under the above legislation enacted against unfair,
10 deceptive, fraudulent, and unconscionable consumer sales practices.

11 139. By knowingly and falsely representing that the CVS Health APAP was fit to be
12 used for the purposes for which they were intended—when in fact they were defective and
13 dangerous—and by other acts alleged, Defendant violated the above statutes, enacted to protect
14 consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices,
15 and false advertising. The UCL prohibits “any unlawful, unfair, or fraudulent business act or practice
16 and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section 17500 of
17 the California Business and Professions Code. Section 17500, in turn, prohibits any untrue or
18 misleading statements made in connection with the sale of goods. The CLRA defines as statutorily
19 unlawful certain unfair methods of competition and unfair or deceptive practices. Cal. Civ. Code
20 § 1750 *et seq.*

21 140. By knowingly and falsely representing that the CVS Health APAP was fit to be
22 used for the purposes for which they were intended—when in fact they were defective and
23 dangerous when used during pregnancy—and by other acts alleged, Defendant violated the above
24 statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable
25 trade and business practices, and false advertising.

26 141. Defendant’s actions and omissions are uncured or incurable, deceptive acts under
27 the above legislation.
28

1 142. Defendant had actual knowledge of the defective and dangerous conditions of the
2 CVS Health APAP but failed to take any action to cure such defective and dangerous conditions.

3 143. Plaintiff Mother relied upon Defendant's misrepresentations and omissions in
4 determining which CVS Health APAP (if any) to ingest.

5 144. Defendant's deceptive, unconscionable, or fraudulent representations and material
6 omissions to consumers constituted unfair and deceptive acts and practices.

7 145. By reason of the unlawful acts in which Defendant engaged, and as a direct and
8 proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

9 146. As a direct and proximate result of Defendant's violations of the above-listed
10 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
11 statutory and compensatory damages in an amount to be proven at trial.

12 **COUNT VI: NEGLIGENT MISREPRESENTATION**

13 147. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

14 148. Defendant had a duty to accurately and truthfully represent to consumers, including
15 Plaintiff Mother, and the public that the CVS Health APAP had not been adequately tested and
16 found to be a safe and effective treatment for pregnant women. Defendant breached that duty as
17 its representations were false.

18 149. Defendant failed to exercise ordinary care in the representations concerning the
19 CVS Health APAP while Defendant was involved in its manufacture, sale, testing, quality
20 assurance, quality control, and distribution in interstate commerce, because Defendant negligently
21 misrepresented the CVS Health APAP's high risk of unreasonable and dangerous adverse side
22 effects.

23 150. Defendant also breached its duty in representing to Plaintiff Mother that the CVS
24 Health APAP had no serious side effects when ingested during pregnancy.

25 151. As a foreseeable, direct, and proximate result of Defendant's negligent
26 misrepresentations, Defendant knew or had reason to know that the CVS Health APAP had been
27 insufficiently tested or had not been tested at all; and that they lacked adequate and accurate
28

1 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
2 adverse side effects. Those side effects include neurodevelopmental disorders in children, such as
3 ASD and ADHD.

4 152. As a direct and proximate result of Defendant's breach of express warranty,
5 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
6 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages
7 to which they may be legally entitled.

8 **PUNITIVE DAMAGES**

9 153. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

10 154. Defendant failed to adequately test and study the CVS Health APAP to determine
11 and ensure that the CVS Health APAP was safe and effective prior to releasing them for sale for
12 human consumption.

13 155. Further, Defendant continued to manufacture and sell the CVS Health APAP after
14 obtaining knowledge and information that they were defective and unreasonably unsafe in that
15 they did not include adequate warnings.

16 156. Defendant was aware of the probable consequences of the dangerous and defective
17 product, including the risk of neurodevelopmental disorders in children, such as ASD and ADHD,
18 when they suffered prenatal exposure.

19 157. At all material times, Defendant knew or should have known that the CVS Health
20 APAP was inherently dangerous with respect to the following: the risk of neurodevelopmental
21 disorders in children, such as ASD and ADHD, when they suffered prenatal exposure; pain and
22 suffering; loss of life's enjoyment; and unsuccessful treatments to cure the conditions proximately
23 related to the use of the CVS Health APAP, as well as the other permanent and lasting severe
24 personal injuries.

25 158. Defendant's misrepresentations included knowingly withholding material
26 information from consumers and the public, including Plaintiff Mother, concerning the safety and
27 efficacy of the CVS Health APAP, which deprived Plaintiff Mother of vitally necessary
28

1 information with which to make a fully informed decision about whether to use the CVS Health
2 APAP.

3 159. At all material times, Defendant also knew and recklessly and/or intentionally
4 disregarded the fact that the CVS Health APAP can cause debilitating and life-altering side effects
5 with greater frequency than safer alternative methods, products, and/or treatments. But Defendant
6 recklessly failed to advise the medical community and the general public, including Plaintiff
7 Mother, of that fact.

8 160. At all material times, Defendant intentionally misstated and misrepresented data;
9 and Defendant continues to misrepresent data so as to minimize the perceived risk of injuries and
10 the rate of complications caused by or associated with the CVS Health APAP.

11 161. Notwithstanding the foregoing and the growing body of knowledge and
12 information regarding the true and defective nature of the CVS Health APAP, with its increased
13 risk of side effects and serious complications, Defendant continues to aggressively market the CVS
14 Health APAP to consumers, including the pregnant community at large, without disclosing the
15 true risk of the complications and side effects.

16 162. When Plaintiff Mother consumed the CVS Health APAP and since then, Defendant
17 has known the CVS Health APAP was defective and unreasonably dangerous without an adequate
18 warning. But Defendant continued to manufacture, produce, assemble, market, distribute, and sell
19 the CVS Health APAP to the pregnant community so as to maximize sales and profits at the
20 expense of the health and safety of expecting mothers in a conscious, reckless, and/or intentional
21 disregard of the likely and foreseeable harm caused by the CVS Health APAP to members of the
22 public, including Plaintiffs.

23 163. At all material times, Defendant has concealed and/or failed to disclose to the public
24 the serious risks and the potential complications associated with the CVS Health APAP, so as to
25 ensure continued and increased sales and profits and to the detriment of the public, including
26 Plaintiffs.

164. Defendant's acts and omissions are of such character and nature so as to entitle Plaintiffs to an award of punitive damages in accordance with applicable statutory and common law. Defendant's conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendant individually, and jointly and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendant, individually, and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. Restitution and disgorgement of Defendant's profits;
- iii. Applicable statutory penalties;
- iv. Punitive or enhanced compensatory damages;
- v. Reasonable attorneys' fees as provided by law;
- vi. Past and future costs of all proceedings;
- vii. All ascertainable economic damages;
- viii. Prejudgment interest on all damages as allowed by law; and
- ix. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands a trial by jury on all issues so triable.

1 Dated: September 9, 2022

Respectfully submitted,

2 /s/ Warren D. Postman

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